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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,893	01/17/2001	Shih-Chieh Hung	11709-003001	6011
26161	7590	11/18/2004	EXAMINER	
FISH & RICHARDSON PC			GARVEY, TARA L	
225 FRANKLIN ST			ART UNIT	PAPER NUMBER
BOSTON, MA 02110			1636	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/761,893

Applicant(s)

HUNG ET AL.

Examiner

Tara L Garvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 20, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9-20 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 12-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9-11 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1, 3-7, 9-11 and 23 are pending. Claims 2, 8, 21-22 and 24-31 were cancelled. Claims 12-20 were withdrawn for being drawn to a non-elected invention.

Response to Amendment

Claim Rejections under 35 U.S.C. § 112, first paragraph

The rejection of claims 1-7, 9-11 and 21-31 under 35 U.S.C. § 112, first paragraph as containing new matter has been withdrawn in view of the Applicants' amendment in which the limitation of "isolating the mesenchymal stem cells prior to cell adherence to the culture device" was removed from the claims.

Claim Rejections under 35 U.S.C. § 102(b)

The rejection of claims 1 and 4-7 under 35 U.S.C. § 102(b) as being anticipated by Caplan et al has been withdrawn in view of the Applicant's amendment which removed the limitation of "isolating the mesenchymal stem cells prior to cell adherence to the culture device" and incorporated the limitation of a culture device that "contains a plate having pores, wherein the pore size is sufficient for separating mesenchymal stem cells from other cells" to claim 1.

New Grounds of Rejection

The new grounds of rejection are necessitated by the Applicants' amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-7, 9-11 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rieser et al (WO 97/46665; USP 6,242,247 is the national stage equivalent to WO 97/46665 and is referenced in the following as it is in English) in view of Bruder et al (USP 5,942,225) and Huss (WO 00/06705; USP 6,361,997 is the

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national stage equivalent to WO 00/06705 and is referenced in the following as it is in English).

Rieser et al teach a method of making implants comprising culturing cells capable of chondrocyte-function, including mesenchymal stem cells (MSCs), in a culture device comprising a porous plate. The plate has pores in the range of 2-20 microns. Rieser et al demonstrate their method using cells obtained from bovine shoulder (therefore mammalian tissue) and the cells thus cultured can differentiate into cartilage. In addition, they teach the cells can be obtained from bone marrow. (See abstract, column 5, lines 15-19, column 7, lines 7-11 and 51-53 and column 8, lines 7-9). Reiser et al do not teach the method wherein the mixture comprising MSCs is human, the MSCs are CD34-negative, uses DMEM-LG medium or recovers the cells from the plate.

Bruder et al demonstrate teach isolating bone-marrow derived human mesenchymal stem cells from the culture device and culturing the cells in DMEM-LG (column 1, lines 8-12, column 3, lines 42-54, column 4, lines 15-35 and column 5, lines 4-40).

Huss demonstrates that mesenchymal stem cells that adhere to the culture surface are CD34-negative (abstract, column 1, lines 6-13 and column 3, lines 11-14).

It would have been obvious to one of ordinary skill in the art to modify the method of Rieser et al to use human mesenchymal stem cells, culture them in DMEM-LG and recover the adherent cells that are CD34 negative. One would have been motivated to do these because DMEM-LG is a well-known culture medium for MSCs, which provides selective attachment for MSCs, which will be CD34-negative and because recovering

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human MSC would have great therapeutic value for various human pathologic conditions such as hematological cancers, bone repair, and cartilage replacement. Absent of any evidence to the contrary, there would have been a reasonable expectation of success in culturing the cells in DMEM-LG and recovering the human MSC for the culture device since these methods have been used with success in previous experiments.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-2917. The examiner can normally be reached on Monday through Friday 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center


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(Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tara L Garvey
Examiner
Art Unit 1636

TLG



JAMES KETTER
PRIMARY EXAMINER